

CLAIMS

1. (currently amended) A tablet having enhanced stability comprising:

(a) up to 50% by weight of at least one excipient; and

(b) at least 50% by weight of a dried extract, the dried extract consisting essentially of ingredients of an aqueous extract of red vine leaves and up to about 10% by weight of colloidal, anhydrous silica, of red-vine-leaves;

~~(b) —up to 50% by weight of an excipient,~~

~~wherein the tablet shows an enhanced stability the dried extract of red-vine-leaves has been produced in a drying process comprising the step of adding at least a proportion of the excipient during the drying process.~~

2–3. (cancelled)

4. (currently amended) The tablet according to claim 1, comprising:

(a) 50% to 70% by weight of the dried extract ~~of red-vine-leaves;~~

(b) 25% to 49% by weight of the at least one excipient; and

(c) 1% to 5% by weight of a tablet film,

based on the total mass of the film coated tablet.

5. (currently amended) The tablet according to claim 1, comprising:

(a) 51% to 59% by weight of the dried ~~aqueous extract of red-vine-leaves;~~

(b) 38% to 48% by weight of the at least one excipient; and

(c) 1 to 3% by weight of a tablet film,

based on the total mass of the film coated tablet.

6. (currently amended) The ~~film-coated~~ tablet according to any one of claims 1 to 5, wherein the at least one excipient (~~b~~) consists essentially of: 70% to 85% by weight of at least one binder, 0.5% to 12.5% by weight of at least one disintegrant, 5% to 15% by weight of at least one filler, and 1% to 5% by weight of at least one lubricant, based on the total mass of the at least one excipient (~~b~~).

7. (currently amended) The tablet according to any one of claims 1 to 5, wherein the at least one excipient comprises a binder, and wherein the binder is powdered cellulose, microcrystalline cellulose, starch, polyvinylpyrrolidone, copolymers of vinylpyrrolidone with other vinyl derivatives, cellulose derivatives, or a mixture thereof.

8. (currently amended) The ~~film-coated~~ tablet according to claim 6, wherein the binder is powdered cellulose, microcrystalline cellulose, starch, polyvinylpyrrolidone, copolymers of vinylpyrrolidone with other vinyl derivatives, cellulose derivatives, or a mixture thereof.

9. (currently amended) The ~~film-coated~~ tablet according to any one of claims 1 to 5, wherein the disintegrant is colloidal silica, sodium starch glycolate, crosslinked polyvinylpyrrolidone (crospovidone), croscarmellose sodium salt (sodium salt of cellulose carboxymethyl ether, crosslinked), sodium-carboxymethylcellulose, dried maize starch, or a mixture thereof.

10. (currently amended) The ~~film-coated~~ tablet according to claim 6, wherein the disintegrant is colloidal silica, sodium starch glycolate, crosslinked

polyvinylpyrrolidone (crospovidone), croscarmellose sodium salt (sodium salt of cellulose carboxymethyl ether, crosslinked), sodium-carboxymethylcellulose, dried maize starch, or a mixture thereof.

11. (currently amended) The ~~film-coated~~ tablet according to any one of claims 1 to 5, wherein the filler is an inorganic phosphate or hydrogen phosphate.

12. (currently amended) The ~~film-coated~~ tablet according to claim 6, wherein the filler is an inorganic phosphate or hydrogen phosphate.

13. (currently amended) The ~~film-coated~~ tablet according to any one of claims 1 to 5, wherein the filler is silicon dioxide, talc, stearic acid, sodium stearyl fumarate, magnesium stearate, or glycerol tribehenate.

14. (currently amended) The ~~film-coated~~ tablet according to claim 6, wherein the filler is silicon dioxide, talc, stearic acid, sodium stearyl fumarate, magnesium stearate, or glycerol tribehenate.

15. (currently amended) The ~~film-coated~~ tablet according to any one of claims 4 and 5, wherein the tablet film (c) consists essentially of: 50% to 85% by weight of at least one film former, 5% to 10% by weight of at least one plasticizer, 10% to 20% by weight of at least one coating agent, and 0% to 15% by weight of at least one colorant, based on the total mass of the tablet film (c).

16. (currently amended) The ~~film-coated~~ tablet according to claim 6, wherein the tablet film (c) consists essentially of: 50% to 85% by weight of at least one film former, 5% to 10% by weight of at least one plasticizer, 10% to 20% by weight of at least one coating agent, and 0% to 15% by weight of at least one colorant, based on the total mass of the tablet film (c).

17. (withdrawn) A process for preparing a film coated tablet comprising:

- (a) mixing a dried aqueous extract of red vine leaves with excipients, optionally in the presence of a volatile diluent;
- (b) optionally screening the mixture obtained;
- (c) compressing the mixture with a suitable tablet press; and
- (d) coating the resulting tablet with a tablet film.

18. (withdrawn) A method for making a film coated tablet containing a dried aqueous extract of red vine leaves comprising:

- (a) extracting red vine leaves with water and drying the extract to obtain a dried aqueous extract of red vine leaves;
- (b) combining the dried aqueous extract of red vine leaves with an excipient consisting essentially of: at least one binder, at least one disintegrant, at least one filler, and a lubricant;
- (c) forming a tablet of the mixture obtained from step (b); and
- (d) coating the tablet with a tablet film consisting essentially of: a film former, a plasticizer, a coating agent, and optionally a coloring agent to obtain a film coated tablet.

19. (withdrawn) The method of claim 18, wherein the dried aqueous extract of vine leaves further comprises an addition of up to 10% by weight of silica based on total amount of the dried aqueous extract of red vine leaves.

20. (withdrawn) The method of claim 19, wherein the silica is colloidal, anhydrous silica.

21. (withdrawn) The method of claim 20, wherein the colloidal, anhydrous silica is added to the dried aqueous extract of vine leaves during drying or before admixing with the other constituents.

22. (withdrawn) A method for making an aqueous extract of red vine leaves comprising:

- (a) collecting red vine leaves at a point of time when the content in flavonoids has reached an optimum;
 - (b) drying and crushing the leaves;
 - (c) cutting the leaves to pieces;
 - (d) extracting the leaves with water at elevated temperatures for 6 to 10 hours;
- and
- (e) concentrating and drying the aqueous extract of red vine leaves.

23. (withdrawn) The method according to claim 22, further comprising adding during the drying process (e) up to 10% by weight of a flow regulator based on the final total amount of the aqueous extract of red vine leaves.

24. (withdrawn) The method according to claim 23, wherein the flow regulator is silica.

25. (withdrawn) The method according to claim 23, wherein the flow regulator is colloidal, anhydrous silica.

26. (withdrawn) The method according to claim 25, wherein the colloidal, anhydrous silica comprises 2.5% to 7.5% by weight based on the final total amount of the aqueous extract of red vine leaves.

27. (withdrawn) The method according to claim 26, wherein the colloidal, anhydrous silica comprises about 4% by weight based on the final total amount of the aqueous extract of red vine leaves.

28. (withdrawn) The method according to claim 22, wherein the leaves in step (d) are extracted with water at temperatures from 60°C to 80°C.

29. (new) The tablet of claim 1, wherein the colloidal, anhydrous silican is present in an amount of about 2.5% to about 7.5 % by weight based on total amount of the dried extract.

30. (new) The tablet of claim 1, wherein the colloidal, anhydrous silican is present in an amount of about 4% by weight based on total amount of the dried extract.